

**IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

<b>UNITED STATES</b>	)	
	)	
<b>Petitioner,</b>	)	<b>Civil Action No. 3:20-cv-00158</b>
	)	
<b>v.</b>	)	<b>Judge Aleta A. Trauger</b>
	)	
<b>FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.</b>	)	<b>Magistrate Judge Jeffery S. Frensley</b>
	)	
<b>Respondents.</b>	)	

**OPPOSITION TO PETITION TO ENFORCE INSPECTOR GENERAL SUBPOENAS**

**I. INTRODUCTION**

The government has petitioned this Court for summary enforcement of subpoenas served on Fresenius Medical Care Holdings and two of its pharmacy subsidiaries. The motion lacks basis in the facts or the law. The government’s subpoenas have been overbroad and unduly burdensome. Fresenius nevertheless has complied with the subpoenas, producing more than a million pages of documents, extensive data, and voluminous patient-specific pharmacy records. It also has provided detailed privilege logs meeting all requirements. The Petition’s demand for still more information from Fresenius is more effort to impose burdens not required by law. In addition, the government has violated Local Rules 7.01(a)(1) and 37.01 of this Court by filing its Petition without prior consultation regarding matters in dispute. The Petition should be denied.

**II. BACKGROUND**

**A. Fresenius Medical Care North America**

Respondent Fresenius Medical Care Holdings (FMCH) is the primary U.S. affiliate of Fresenius Medical Care AG & Co. KGaA, a German company. FMCH, in turn, is a holding company that owns other affiliated companies that do business in the United States under the trade

name Fresenius Medical Care North America (FMCNA). FMCNA operates more than 2,400 dialysis clinics. Its nurses and clinical staff treat patients who suffer from kidney failure so acute that they require dialysis or a transplant to survive.

The dialysis patients are under the care of physicians. These physicians prescribe the dialysis treatment and related therapies that are then implemented by FMCNA nurses. The prescribing physicians are not employed by FMCNA but do have admitting privileges and may round on patients at the clinics. FMCNA, through other affiliates, also manufactures or distributes dialysis products used in the clinics.

## **B. FMCNA Enters the Pharmacy Business**

Treating physicians often prescribe drugs for their patients. Prescriptions for intravenous drugs used during dialysis treatments in clinics (such as those treating anemia) are acquired by FMCNA and administered by FMCNA staff. These drugs are purchased by FMCNA, and reimbursement to FMCNA is included in the flat, bundled payment that Medicare makes for providing a dialysis treatment. These IV drugs are not at issue in this investigation.

Physicians also commonly prescribe certain oral medications to be taken by dialysis patients at home. These prescriptions are filled by pharmacies. Typical oral dialysis-related home medications include phosphate binders. These binders are taken by patients when they eat. They help patients excrete excess phosphorous. (Kidney failure can lead to excess phosphorous in the blood.) These dialysis-related home medications are at issue in this matter.

Government payers such as Medicare compensate FMCNA for performing dialysis treatments under a flat per-treatment rate called the “composite” or “bundled” rate. The “bundle” of services covered by that flat rate has changed over time, but historically it did not include the oral, home medications. In approximately 2009, Medicare stated an intention to expand the

“bundle” to include those drugs. In response to that statement, FMCNA and other dialysis providers initiated pharmacy subsidiaries to provide these drugs as part of the bundled dialysis services for their patients. While the dialysis providers opened pharmacies to meet the expected requirement, Medicare decided to defer including these drugs in the bundle. In the meantime, however, dialysis providers such as FMCNA started offering pharmacy services to patients.

Fresenius’ pharmacies are collectively known as FreseniusRx. If an FMCNA dialysis patient chooses, FreseniusRx will fill prescriptions for oral dialysis-related drugs. (FreseniusRx does not fill non-dialysis prescriptions for patients.) FreseniusRx has procedures governing how patients choose to use FreseniusRx and other aspects of its business. At present, Medicare reimburses FreseniusRx just as it does any commercial pharmacy.

### **C. FreseniusRx Has a Need for Legal Advice**

Dialysis is a heavily regulated industry. FMCNA was well versed in that regulated environment. However, FreseniusRx was a relative newcomer to the pharmacy industry, which itself is separately heavily regulated at both the state and federal levels. Multiple state and federal agencies have jurisdiction over pharmacy operations. In light of the regulatory environment of the pharmacy business, FreseniusRx required legal assistance to create policies and procedures that would comply with these complex but often ambiguous regulations. FreseniusRx also is a major commercial enterprise, with many contracts requiring legal assistance. For these reasons, FreseniusRx has had a need for very substantial legal advice over its formative years on multiple subjects. This advice was obtained from two sources—FMCNA’s internal legal department and outside counsel.

FMCNA lawyers Ben Daniels and Jim Jacobson were assigned to assist FreseniusRx. FMCNA also has other internal lawyers who assist with ensuring compliance with the federal and

state rules and regulations that apply to its businesses. These lawyers included David Kembel and Doug Kott, as well as several others reflected on the privilege logs. Outside counsel included Arnold & Porter, Bass Berry & Sims, and other firms. Specific topics upon which legal advice was given are discussed below and on the privilege logs.

**D. The Middle District Subpoenas to FreseniusRx**

As an FMCNA affiliate serving dialysis patients, FreseniusRx must participate in the Medicare program. Like all healthcare companies, it receives inquiries about its compliance with federal and state regulations. These inquiries often are precipitated by “whistleblower” complaints and underlying *qui tam* complaints. Fresenius has received multiple government administrative subpoenas over the past four years such as the Middle District of Tennessee subpoenas at issue here. Typically, and FMCNA understands it to be the case here, these subpoenas relate to a sealed FCA complaint filed before the first subpoena is issued. Here, these subpoenas were served long ago, starting in 2016. Accordingly, Fresenius understands this Petition to be another effort by the government to extend the time to decide whether to intervene on a now very stale *qui tam* complaint. As a consequence of this delay and the fact that the *qui tam* complaint is still under seal, Fresenius has no notice of the allegations against it. Because no complaint has been publicly filed against Fresenius, Fresenius also has no recourse to Rule 26 or motion practice that might limit the government’s overly broad and unduly burdensome discovery.

Over the past four years, Fresenius and the government have engaged in extensive communications regarding the subpoenas at issue. An understanding of the full correspondence is important to appreciate the overbreadth of the government’s requests and Fresenius’ efforts at compliance. As such, and given the extraordinary relief sought by the government, Fresenius attaches a full set of this correspondence as Exhibits 1-132. It also provides a chronology of these

communications as Exhibit A hereto. This correspondence started with the issuance of the first administrative subpoena now at issue, which was issued out of the Northern District of Texas and served on June 28, 2016. Ex. 1. This subpoena sought extensive documentation regarding Fresenius and its pharmacies, including documents related to marketing and refills. *Id.* The next subpoenas were served on May 2, 2017, out of the Middle District of Tennessee. Exs. 38-40; ECF 4-1, 4-2, 4-2. These requests also sought documents about marketing and refills and many other subjects. *Id.* On September 19, 2018, the Middle District of Tennessee requested extensive documentation about 120 specific patients. Exs. 66, 71, 73. The subpoenas overlapped extensively, and Fresenius produced documents in both the Northern District of Texas and the Middle District of Tennessee. The Northern District of Texas has no open disputes with Fresenius.

**E. Fresenius' Responses to the Subpoenas**

Fresenius has produced documents in response to the subpoenas. The response effort has been massive and burdensome. Fresenius has produced more than 1.3 million pages and more than 350,000 documents. Exs. 80, 103, 116; ECF 3-9, 3-12, 3-17. It has extracted and produced extensive data from current and obsolete computer systems. Exs. 49, 51-54, 58-65. It has produced all records requested for 120 patients, including tens of thousands of more pages. Exs. 83-89, 91-102, 106-109, 112, 118. It has spent more than \$3.4 million in attempting to comply with these subpoenas and its lawyers have spent more than 5,600 hours on the matter.

The government initially sought electronic documents from Fresenius employees. The government and Fresenius agreed on the names of employees likely to have relevant information. Exs. 11, 16, 19, 20, 26, 27, 45. The parties also agreed to search terms for those documents. Exs. 24, 29-31, 35-37, 45, 48; ECF 3-4. The government contemplated Fresenius producing these documents based on search terms “without individual review for responsiveness.” Ex. 36.

Fresenius agreed to do so. *Id.* The government was given the documents in an electronic and searchable format. The production involved hundreds of thousands of emails from approximately 20 Fresenius employees. Exs. 80, 116; ECF 3-9, 3-17.

In addition, the government requested electronic data from Fresenius. Exs. 38-40. The requests sought data regarding specific medications. *Id.* The government also sought patient-specific information about drugs, prescriptions, refills, claims, and accounts receivables. *Id.* Fresenius IT wrote programs to provide this information. Exs. 51-54. Due to the dates included, Fresenius had to restore access to archival systems no longer in use. *Id.* For some requests, FreseniusRx retained an outside vendor to obtain data from retired systems. Exs. 58-65.

In September 2018, the government requested “[a]ll of Fresenius’ patient files” for 120 specific patients. Exs. 66, 71-73. Fresenius produced these documents after a time-intensive and extensive manual effort. Fresenius provided over 1500 pages of electronic data for the 120 patients. Exs. 77-78. It then conducted a manual review of records to identify records related to the requested patients. As Fresenius advised the government, this effort “would take significant time and effort to compile,” involving manually “clicking on each file, saving it one by one, and sometimes converting the image to another format such as PDF.” Exs. 83-89, 91. Fresenius produced over 28,500 pages of patient files in this manner. Exs. 92-102, 106-109, 112, 118.

#### **F. The Privilege Logs**

Fresenius and the government agreed on the procedure to be used for identifying privileged documents. Exs. 35-36, 48, 116; ECF 3-4, 3-17. The starting point was documents that contained words or names (such as names of known attorneys) that indicated a privilege might apply. *Id.* Documents that included potential privilege terms then would be manually reviewed by Fresenius for potential production or for inclusion on a privilege log. *Id.*

This manual review was required for over 155,000 documents. Exs. 80, 116; ECF 3-9, 3-17. Reviewing attorneys recorded information including privilege type, production treatment (to withhold or produce with redactions), document type, and a description of the basis for the privilege. Ex. 80; ECF 3-9. The log was generated using available metadata for fields such as date and author. Exs. 80, 116; ECF 3-9, 3-17. It was produced in a searchable Excel format on October 22, 2018. Exs. 74, 80; ECF 3-7, 3-9.

Four months later, on February 13, 2019, the government requested a revision to the log. It asked for separate logging of emails and attachments and separate logging of redactions. Ex. 79; ECF 3-8. Fresenius revised its log accordingly and provided its amended logs on May 10, 2019. Ex. 90; ECF 3-10. On July 30, 2019, the government requested clarification of which documents were attachments and requested a manual review (versus metadata) of certain fields in the logs, such as author and date. Ex. 100; ECF 3-11. This request required extensive work by Fresenius and Fresenius provided its revised privilege logs in September 2019. Exs. 116, 120, 123; ECF 3-17, 3-18, 3-19.

Also in September 2019, Fresenius invited the government to discuss any specific entries it had questions about, writing, “[i]f there are still specific entries about which you have questions or concerns, we are happy to discuss those with you.” Ex. 116; ECF 3-17. The government raised no objection to Fresenius to this second revision to the log. Ex. A. It also did not ask to discuss the basis for the claimed privilege for any entries. *Id.*

#### **G. Identification of Non-Lawyers on the Log**

On February 13, 2019, the government asked Fresenius to provide an index of persons named in the log. Ex. 79; ECF 3-8. Fresenius understood this request was designed to allow the government to ascertain the identities of attorneys to evaluate claims of privilege. On February 27,

2019, Fresenius agreed to provide an index of in-house and outside attorneys. Exs. 80, 82, 85; ECF 3-9. Fresenius provided the index of attorneys. Ex. 90; ECF 3-10. For non-lawyers, Fresenius also provided to the government job titles for email custodians, organization charts, and emails that identified job positions. Exs. 2, 3, 16, 19, 36, 44-46; ECF 3-1, 3-2. Fresenius wrote that “[t]his should resolve the issue,” but offered that if the government had “questions about the roles of non-lawyers on the emails even after your review of other emails and the organization charts we have produced, please let us know and we can discuss that.” Ex. 80; ECF 3-9. The government responded by stating, “Thank you for the update. I look forward to receiving the updated information....” Ex. 82. The government never asked any further questions about the roles of non-lawyers on the logs. Ex. A.

#### **H. Production of Information Covered by the GDPR**

As discussed above, FMCH is a subsidiary of Fresenius AG, a German company. FMCNA employees engage in email correspondence and data exchanges with the employees of its European affiliates. These European individuals are entitled to the protections of the EU’s General Data Protection Regulation (“GDPR”), which regulates the “processing of personal data.” GDPR at Article 2(1). The GDPR defines personal data to mean, “any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier....” *Id.* at Article 4(1). It defines “processing” to mean “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available....” *Id.* at Article 4(2). The GDPR



applies “regardless of whether the processing takes place in the [EU] or not.” *Id.* at Article 3(1). While the GDPR has certain exceptions, their application can be a fact-intensive inquiry and requires a balancing of the interests of third parties against the interests of the employees.

As the U.S. subsidiary of a German company, Fresenius deals routinely with the GDPR. Indeed, at the same time Fresenius was responding to these subpoenas, it also was facing identical GDPR issues with an unrelated subpoena issued by the DOJ in Denver. On August 1, 2019, Fresenius sent nearly identical letters to the Denver DOJ and to the Middle District of Tennessee that provided further clarification of the issue. Exs. 103-104; ECF 3-12. The letters discussed the inherent conflict between the GDPR and discovery in the United States. *Id.* On September 10, 2019, Fresenius provided the Middle District of Tennessee further information about its position regarding the GDPR and offered a procedure for resolution of the issue. Ex. 113.

Fresenius received a response from the DOJ in Denver, and the matter there was amicably resolved through a procedure involving redaction, production, and logging that gave due weight to the GDPR and the DOJ’s needs. Exs. 127, 129. In this Tennessee matter, the government did not respond to Fresenius’ proposal. Ex. A.

### **III. ARGUMENT**

This Petition to Enforce is not supported in the law or the facts. Fresenius has *not* failed to respond to these subpoenas. Rather, it has produced a massive amount of documents and data. Its privilege log, moreover, meets all legal requirements. Fresenius welcomes an *in camera* review of its privilege determinations and its log. It would be a means of providing some court supervision of the government’s overbroad document requests and its unsupported demands regarding privilege logs. However, Fresenius does not believe that the government has shown that such a review is necessary.

**A. Fresenius Has Not Refused to Obey the Subpoenas**

The sole statutory authority cited by the government is the Inspector General Act, which states that the government is authorized:

(4) to require by subpoena the production of all information, documents, reports, answers, records, accounts, papers, and other data in any medium (including electronically stored information), ... , *which subpoena, in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court....*

5 U.S.C. § APP. 3 § 6(a)(4) (emphasis added). As shown by Fresenius' production and logging efforts described above, this is not a "case of contumacy or refusal to obey."

The government cites no case where a Petition for Summary Enforcement was used for the sole purpose of seeking a revised privilege log or *in camera* review where the respondent complied with all requests. Rather, petitions for enforcement serve as a mechanism to enforce an administrative subpoena when the recipient *refuses* to comply with all or a portion of the subpoena. *See, e.g., Arctic Exp. v. U.S.*, 134 F.3d 370 (6th Cir. 1997); *U.S. v. Markwood*, 48 F.3d 969, 974 (6th Cir. 1995); *Consumer Fin. Prot. Bureau v. Harbour Portfolio Advisors*, 2017 WL 631914, at \*2 (E.D. Mich. 2017); *Miami-Luken v. U.S. Dep't of Justice*, 2016 WL 3855205, at \*3 (S.D. Ohio 2016).

**B. The Government Has Violated the Rules of This Court**

While Fresenius has met its discovery obligations, the government has not. Local Rules 7.01(a)(1) and 37.01 require discussion between counsel before the filing of discovery motions. Similarly, the Practice and Procedure Manual provides that, "if counsel have not spoken to each other in an effort to resolve the dispute, or if there is any uncertainty about whether counsel have spoken to each other, the motion to compel or for sanctions will be denied." Magistrate Judge Jeffery S. Frenesley, Practice and Procedure Manual, at III.D. 4-5. *See also Kasper v. AAC*

*Holdings*, 2017 WL 6353294, at \*6 (M.D. Tenn. 2017) (Frensley, J.) “(Plaintiffs initially failed to include a Certification of Good Faith Effort as required by Local Rule 37.01(b)(3)... Plaintiffs are advised that adherence to the Local Rules is not optional in this forum.”). Specific to this Petition, this Court’s Administrative Order 174-1 includes a “Checklist for Rule 26(f) Meet and Confer Regarding ESI,” which suggests parties discuss whether they “can agree upon alternative ways to identify documents withheld on the grounds of privilege or work produce to reduce the burdens of such identification.”

The government has not complied with these rules. Fresenius provides a chronology of communications specific to issues raised in the Petition as Exhibit B hereto. This Petition was filed five months after the government’s last substantive contact with Fresenius. Exs. A, B. The government complains of issues in the Petition that it never raised to Fresenius (i.e., its log descriptions for attorney client and work product privilege). *Id.* Also, Fresenius offered to resolve material aspects of the relief requested in this Petition, including offering to discuss (a) any specific privilege log entry that the government questioned to explain the basis of the privilege (Ex. 116; ECF 3-17); (b) job information about non-lawyers on its privilege log (Ex. 80; ECF 3-9); and (c) reaching agreement on the GDPR issue in an approach approved by the DOJ in another matter (Ex. 113). All Fresenius’ offers were met with silence. Exs. A, B.

Many courts have denied motions for failure to comply with Local Rule 37.01(a). *See, e.g., Hugueley v. Parker*, 2020 WL 636579, at \*2 (M.D. Tenn. 2020); *Am. Cas. Co. v. Crescent Enterprises*, 2014 WL 1515561, at \*1-2 (M.D. Tenn. 2014). As one court has stated:

“This prerequisite [of a good faith certificate] is not an empty formality. On the contrary, it has been the Court’s experience that obliging attorneys to certify to the Court that they conferred in good faith results, in a large number of cases, in resolution of the discovery disputes by counsel without intervention of the Court. *Thus, the requirement of a certificate cannot be satisfied by*

*including with the motion copies of correspondence that discuss the discovery at issue. Rather, both attorneys must certify that they conferred on the discovery issues in an attempt to resolve them. The Court is unwilling to decipher letters between counsel to conclude that the requirement has been met.”*

*D & S Remodelers v. Foundry*, 2016 WL 10651866, at \*4 (M.D. Tenn. 2016) (emphasis added). See also *Burges v. BancorpSouth*, 2017 WL 4640462, at \*2–3 (M.D. Tenn. 2017) (purpose of the Local Rule is to eliminate the need for the Court to expend scarce resources on discovery disputes which can be amicably resolved and to ensure the most efficient allocation of the Court’s resources).

The meet-and-confer requirement of these rules is not a formality—it is intended to ensure that the Court’s resources are called upon only when there is a true, intractable dispute. Here, motion practice may have been avoided. The cooperation and professional communication between Denver DOJ and Fresenius is a perfect example of conferral obviating motion practice, as the locals rules here are designed to do. In contrast to Nashville DOJ’s silence followed by motion practice, the GDPR issues in the Denver matter were amicably resolved through conferral that resulted in an agreed-upon procedure involving redaction, production, and logging that gave due weight to the GDPR and the DOJ’s needs. Exs. 127, 129. Tellingly, here, for each of the privilege log issues that the government did raise with Fresenius before filing its Petition, Fresenius addressed them. Ex. B. There is no reason to think it would not have done so with the additional, new issues. Based on the government’s violations, the Court should dismiss this Petition.

### **C. The Petition Has No Merit**

Fresenius has met all reasonable requirements for responding to the subpoenas. The government seeks expansive relief, but a district court “is not a ‘rubber stamp’ for agency demands for the production of information.” *Markwood*, 48 F.3d at 979. Fresenius is entitled to assert

privilege over (and obtain a court ruling regarding) the production of documents in response to administrative subpoenas. *Upjohn v. U.S.*, 449 U.S. 383, 396-97 (1981); *U.S. v. Euge*, 444 U.S. 707, 714 (1980); *Linde Thomson v. Resolution Tr.*, 5 F.3d 1508, 1513 (D.C. Cir. 1993); *U.S. v. Brown*, 223 F. Supp. 3d 697, 703 (N.D. Ohio 2016). Indeed, there is an essential “independent role which the federal courts play in subpoena enforcement proceedings[.]” *Consumer Fin. Prot. Bureau v. Accrediting Council for Indep. Colleges*, 854 F.3d 683, 689 (D.C. Cir. 2017). Importantly, “federal courts stand guard against abuses of the subpoena-enforcement processes.” *Id.* Such abuse has taken place here with the government’s continuing demands for more documents and additional information. Ex. A.

Fresenius’ privilege log (including its document descriptions) meets all legal requirements. This Court’s Administrative Order 174-1 directs that if a privilege log is produced, “the Court expects the parties to discuss foregoing using traditional document-by-document logs in favor of alternate logging methods, such as identifying information by category or including only information from particular metadata fields (e.g., author, recipient, date).” The government here has refused to accept a log that did not separately enter, “document-by-document,” email attachments (even though Fresenius had already logged the emails individually) and has further refused to accept a log that used metadata for the “author, recipient, date” fields. ECF 2, pp. 14-15. Courts encourage flexibility in preparation of privilege logs to avoid undue burden. *Shufeldt v. Baker, Donelson*, 2020 WL 1532323, at \*5 (M.D. Tenn. 2020) (“Where a document-by-document privilege log would be unduly burdensome, courts have permitted a categorical log.”); *Ajose v. Interline Brands*, 2016 WL 6893866, at \*1-3 (M.D. Tenn. 2016).

Privilege logs do not require extensive information. Nor do they require so much detail that the privileged information is disclosed. Rather, ““a person seeking to assert the attorney-client

privilege must make a minimal showing that the communication involved legal matters. This showing is not onerous and may be satisfied by as little as a statement in the privilege log explaining the nature of the legal issue for which advice was sought.” *Carhartt v. Innovative Textiles*, 333 F.R.D. 118, 121 (E.D. Mich. 2019). “Strict adherence” to an adversary’s privilege log requirements is not required, particularly in cases involving voluminous discovery. *See, e.g., Phillips v. C.R. Bard*, 290 F.R.D. 615, 637-38 (D. Nev. 2013) (quoting Rule 26 advisory committee notes stating, “[d]etails concerning time, persons, general subject matter, etc., may be appropriate if only a few items are withheld, but may be unduly burdensome when voluminous documents are claimed to be privileged or protected, particularly if the items can be described by categories.”).

**D. Fresenius’ Logs Meet All Legal Requirements and No Waiver is Present**

The government asks the Court to find a waiver of privilege. ECF 2, pp. 35-39. This request has no legal basis. “Waiver is an ‘extreme sanction’ typically ‘reserved for cases of unjustifiable delay, inexcusable conduct, and bad faith in responding to discovery requests.’” *Shufeldt*, 2020 WL 1532323, at \*6 (waiver unjustified where party delayed providing log for more than a year and then provided insufficient single-page log with broad categorical claims); *Hobart v. Dayton Power*, 2017 WL 3668848, at \*2 (S.D. Ohio 2017) (waiver unjustified where party failed to assert attorney-client privilege at all as a basis for withholding documents). *See also Am. Nat. Bank v. Equitable Life Assur. Soc. of U.S.*, 406 F.3d 867, 879 (7th Cir. 2005); *U.S. v. British Am. Tobacco*, 387 F.3d 884, 890-91 (D.C. Cir. 2004); *Perez v. Mueller*, 2016 WL 6882851, at \*5 (E.D. Wis. 2016); *In re: Fluidmaster*, 2016 WL 6599947, at \*5-6 (N.D. Ill. 2016); *Exec. Mgmt. Servs. v. Fifth Third Bank*, 309 F.R.D. 455, 464-65 (S.D. Ind. 2015).

None of the cases cited by the government support a finding of waiver. In two cases, the court refused to find a waiver. *NLRB v. NPC Int’l*, 2017 WL 634713, at \*5, \*9 (W.D. Tenn. 2017)

(no bad faith where respondent did not produce log until it responded to the application to enforce the subpoena); *Mafcote v. Fed. Ins. Co.*, 2010 WL 1929900, at \*6 (W.D. Ky. 2010) (“we do not think that imposing a sanction of waiver is justified at this time given counsel’s apparently good-faith (if poorly executed) attempt to comply with the magistrate’s order on short notice.”).

The remaining cases cited by the government are very different from this case. In *Universal City Dev. v. Ride & Show Eng’g*, 230 F.R.D. 688, 690, 698 (M.D. Fla. 2005), waiver was based on the party making only a general privilege objection and “[t]he most serious failure to protect the privilege” arose from the party’s “knowing and voluntary release of privileged documents to a third party.” *In re Haynes*, 577 B.R. 711, 740 (Bankr. E.D. Tenn. 2017), found waiver existed when party was given “multiple chances” by the court to comply. And, in *Nationwide v. Kelt*, 2015 WL 1470971, at \*8, 12 (M.D. Fla. 2015), the court found waiver when the log stated only “Correspondence Between Various Nationwide Personnel” and where Nationwide “did not provide additional information even after Defendants called the inadequacy of the log to Nationwide’s attention.”<sup>1</sup>

The log demonstrates (and Fresenius’ review confirms) that documents at issue are privileged. They include core attorney client advice, as shown in the following samples:

- FMCRx-MDTN-Priv3-00000515-516: Vice President Bob Loeper emails attorney Jim Jacobson seeking legal advice regarding the clinic

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<sup>1</sup> The government cites *Fresenius v. Hood*, 269 So. 3d 36 (Miss. 2018). *Hood* involved a Mississippi chancery state court for DeSoto County interpreting Mississippi state law in a case brought by the Mississippi Attorney General. The same log at issue in *Hood* was used by Fresenius for many federal cases filed in the U.S. District Court for the District of Massachusetts on the same subject. See *In re Fresenius Granuflo/NaturaLyte Dialysate Prod. Liab. Litig.*, MDL No. 13-02428-DPW. The log met all federal requirements. Moreover, *Hood* is contrary to law in this District which holds that email threads need not be separately itemized on a privilege log. See *EPAC Techs. v. Thomas Nelson*, 2015 WL 13729725, at \*5 (M.D. Tenn. 2015). *Hood* also is factually distinguishable. Here, Fresenius agreed, in part because of the *Hood* ruling, to separately log parent emails and attachments and provide detailed information for each entry, consistent with the *Hood* ruling. *Hood* provides no support to the government here.

medication return process in the State of Florida, and Jacobson provides such advice.

- FMCRx-MDTN-Priv3-00000609: Attorney Doug Kott prepares a draft memorandum for prescribers reflecting his legal advice regarding delivery of ESRD-related oral medications to Fresenius patients. Kott then circulates this draft memorandum to key executives and the pharmacy counsel Ben Daniels.
- FMCRx-MDTN-Priv3-00006206: Senior executives seek legal advice regarding the propriety of discussing co-payment amounts with prospective patients. Attorney Ben Daniels provides legal advice on this issue and seeks additional information in order to facilitate his request for further legal advice from Arnold & Porter.
- FMCRx-MDTN-Priv3-00004225-226: A Fresenius executive emails in-house counsel Domenic Gaeta to seek legal advice regarding a draft application.
- FMCRx-MDTN-Priv3-00006105: FreseniusRx VP Michelle Dias requests legal advice from attorney Daniels regarding proposed language on patient co-payments for pharmacy collateral.
- FMCRx-MDTN-Priv3-00006219-220: FreseniusRx Marketing Director emails attorney Daniels a draft presentation on patient co-payment issues, for the purpose of obtaining legal advice on the draft.
- FMCRx-MDTN-Priv3-00000339: Fresenius counsel David Kembel copies attorney Kott and outside counsel on an email to Fresenius executive Bill Valle, in which Kembel provides legal advice and analysis, as well as provides information to other counsel to obtain their legal advice, regarding different copay assistance programs for pharmacy patients.
- FMCRx-MDTN-Priv3-00005858: Attorney Jacobson emails legal advice regarding the indigent waiver program at FreseniusRx, which is then discussed in a series of emails.

The sufficiency of the log is further demonstrated by the specific examples raised by the government in its brief. The government provides two examples of descriptions it deems inadequate. One relates to an e-mail regarding a weekly call (and attached documents) concerning Fresenius' bone-health patient initiative (FMCRx-MDTN-Priv3-00000001). ECF 2, pp. 31-32. The lawyer on the e-mails was David Kembel, who was providing legal analysis on multiple issues related to that program.

This privilege log entry meets all requirements of the law. It lists (1) the author, (2) the



date, (3) all recipients (including copies), (4) the email custodian, (5) the email subject, (6) the privilege type (“Attorney/Client”), and (7) a document description. ECF 3-21, p. 1. Fresenius separately identified the attorney (David Kembel) on the document. *Id.* Moreover, the document description on the log is detailed. It states: “Email providing information to counsel for the purpose of obtaining legal advice and conveying request for legal advice regarding bone mineral metabolism initiative.” *Id.* Fresenius has re-reviewed this document and confirms that the description is accurate. The email attaches a document including a discussion of the legal approach being taken for the “bone metabolism initiative,” a program designed to help patients with bone health. The document also includes as an agenda item a “legal update” from David Kembel. The document then describes that update Mr. Kembel was to provide.

The government also attacks the description of a document related to co-pay card programs (FMCRx-MDTNPriv3-00004306). ECF 2, p. 29-30. This document is privileged and was properly withheld. As the log explains, it involved an “Email chain seeking and containing legal advice ... and strategy of counsel regarding co-pay card programs.” ECF 3-21, p. 1496. The lawyers involved were Doug Kott, Domenic Gaeta, and Jeff Handwerker of Arnold & Porter, each of whom was engaged in providing or seeking legal advice on the matter. *Id.* Fresenius has re-reviewed this document and affirms that the e-mails involve core attorney-client advice on the subject identified in the log.<sup>2</sup>

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<sup>2</sup> The government does not challenge the attorney-client designation for this document. It complains only of the work-product designation. Thus, the parties agree that the document was properly withheld. The line between privilege and work product can be difficult to define, especially in documents such as this one that address compliance with federal laws that give litigation rights to the government. No litigation came out of this issue, and the document is unquestionably privileged. Thus, upon further review and to narrow the issues in dispute in this Petition and avoid the need for court involvement, Fresenius withdraws its claims of work product for this document and certain other documents as explained in correspondence attached as Exhibit

These specific descriptions meet all legal requirements to describe the “nature of the legal issue for which advice was sought.” *Carhartt*, 333 F.R.D. at 121 (denying motion to compel more detailed privilege log that contained the description: “Document(s) providing, containing, reflecting, or discussing confidential advice from counsel concerning anticipated litigation.”). Fresenius’ descriptions meets the standards found in the cases discussed by the government because the log “specified the nature of the legal issue for which advice was sought.” ECF 2, p. 31 (citing *Firefighters’ Ret. Sys. v. Citco*, 2018 WL 305604, at \*6 (M.D. La. 2018) (“each entry includes a description of the document on which privilege is claimed. These descriptions do more than simply state ‘legal advice.’ For each entry, the subject matter of the purported legal advice is also provided.”)).

#### **E. Specific Areas of Disagreement**

The government also attacks some specific aspects of Fresenius’ log. As next discussed, these grievances lack support. Fresenius will discuss each in turn.

##### **1. Entries Where Lawyers are “cc” or Not on Particular Emails**

The government complains about entries where lawyers are copied or where legal advice is discussed among non-lawyer Fresenius executives. ECF 2, p. 15, 33-34. There is no requirement that lawyers author documents for the privilege to apply. Nor is privilege waived if Fresenius executives discuss among themselves legal advice received. Fresenius addressed these points with the government in its September 13, 2019 letter. Ex. 116; ECF 3-17. Fresenius provided by bates range specific examples of documents where non-lawyers were discussing legal advice or obtaining information for lawyers. *Id.* Such documents retain their privilege:

“In the corporate context, the attorney-client privilege extends to

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C. These documents all were properly withheld; the government makes no challenge to the privilege designation in *any* of the documents identified in its Ex. 22. ECF 3-26.

communications, between non-attorney employees, made to obtain or relay legal advice.

As a result, [a] document need not be authored [by] or addressed to an attorney in order to be properly withheld on attorney-client privilege grounds. First, ... documents subject to the privilege may be transmitted between non-attorneys to relay information requested by attorneys. Second, documents subject to the privilege may be transmitted between non-attorneys ... so that the corporation may be properly informed of legal advice and act appropriately.”

*McCall v. Procter & Gamble*, 2019 WL 3997375, at \*4 (S.D. Ohio 2019); *see also* *Ajose*, 2016 WL 6893866, at \*8 (M.D. Tenn. 2016) (“In the corporate context, the attorney-client privilege may extend to communications between employees that convey legal advice given by an attorney to the corporation”). In fact, partly for this reason, courts have held that, “e-mail threads are not required to be separately itemized on privilege logs.” *EPAC Techs.*, 2015 WL 13729725, at \*5. Thus, the Court should reject the government’s argument that emails without a lawyer as sender or recipient are per se not privileged.

## **2. Fresenius Has Properly Asserted Work Product**

In its Exhibit 22, the government challenges all of Fresenius’ work product designations. ECF 3-26. FreseniusRx has not been in any material litigation over any of the matters underlying the documents protected by work product. It has not been sued by any state or federal government. It has not been involved in any litigation with a business partner. Yet, as to the documents upon which Fresenius still claims both work product and privilege, both doctrines provide protection from production.

Actual litigation is not required. A party may assert work product if it had a reasonable *anticipation* of litigation. *In re Professionals Direct Ins.*, 578 F.3d 432, 439 (6th Cir. 2009). Important for FreseniusRx, the doctrine extends to administrative and regulatory proceedings, such as those that might be brought by state pharmacy boards. *Baker v. Chevron*, 2009 WL 10679629,

at \*5 (S.D. Ohio 2009); *U.S. v. Roxworthy*, 457 F.3d 590, 595 (6th Cir. 2006). Similarly, FreseniusRx's work product on matters unrelated to the issues raised by the subpoenas is still protected. *See U.S. v Leggett & Platt*, 542 F.2d 655, 660 (6th Cir. 1975).

Fresenius' privilege log adequately identifies the nature of its work product claim. The log entries "clearly state who authored the document, the date it was created, the recipients, including carbon copies, whether the sender or recipient is an attorney, the type of document (e.g., an email chain), the privilege claimed (e.g., attorney-client and/or work product), and a description of why privilege is claimed (e.g., it discusses or contains reflections on confidential legal advice or work product)." *Carhartt*, 333 F.R.D. at 121. No more is required.

There is no requirement to provide detailed analysis of the potential litigation. Regardless, to provide some context for the type of work product claims at issue, Fresenius asserts work product protection regarding the following documents:

- In 2011, FreseniusRx anticipated litigation arising from an agreement with Lipscomb University governing a clinical training program for its pharmacy students. *See* FMCRx-MDTN-Priv3-5155; 5158.
- In 2013, FreseniusRx faced an inquiry from the Tennessee Board of Pharmacy related to its practice of delivering oral medications outside of Tennessee. *See* FMCRx-MDTN-Priv3-1078.
- In 2013, FreseniusRx was informed of an anonymous complaint filed with the Tennessee Board of Pharmacy regarding pharmacy practice laws. Fresenius retained outside counsel to conduct a comprehensive audit. *See* FMCRx-MDTN-Priv3-509; 941; 2080; 4507; 4609; 4611; 6951.
- In 2013, FreseniusRx received customer and employee complaints, and it retained outside counsel to conduct a comprehensive audit of the facility. *See* FMCRx-MDTN-Priv3-891; 928.
- In 2014, FreseniusRx anticipated potential litigation involving the Washington (State) Pharmacy Quality Assurance Commission relating to a shared pharmacy services arrangement with fulfillment partners WellDyne and DaVita and it conducted legal analysis regarding those issues. *See* FMCRx-MDTN-Priv3-697-698; 4538.
- In 2015, FreseniusRx anticipated possible litigation related to proposed

amendments to a pharmacy agreement with DaVita. *See* FMCRx-MDTN-Priv3-6560.

- In 2016, FreseniusRx needed to address an outside auditor’s comments regarding compliance with the Florida State Board of Pharmacy’s rules. *See* FMCRx-MDTN-Priv3-311.
- In 2016, Fresenius prepared a risk assessment regarding a possible repayment obligation, a Tennessee Board of Pharmacy Complaint, a HIPAA issue, an Illinois state audit and claim, and a CMS inquiry. *See* FMCRx-MDTN-Priv3-7950.

### **3. Identification of Non-Legal Personnel**

The government argues that Fresenius’ logs must “identify third-parties and non-legal personnel by providing any information on their roles or capacities.” ECF 2, pp. 8, 24-28. The government’s request, again, goes well beyond the requirements of this Court’s Administrative Order 174-1 favoring categorical logs or logs “including only information from particular metadata fields (e.g., author, recipient, date).” This is particularly so here, where the size of Fresenius’ logs—and the number of non-legal personnel on them—is directly dictated by the overbreadth of the government’s subpoena. It would be an extreme burden for Fresenius to identify the hundreds of non-legal personnel on its logs. The government cites no Sixth Circuit authority analyzing and requiring such an onerous requirement in a case like this.

On February 27, 2019, Fresenius agreed to identify the lawyers whose names appear on the logs. Ex. 80; ECF 3-9. This approach would permit the government to assess the claim of privilege. *Id.* Fresenius further explained that the organization charts and emails produced provided information regarding the roles of non-lawyers. *Id.* It proposed to the government at that time that, “[i]f you have questions about the roles of non-lawyers on the emails even after your review of other emails and the organization charts we have produced, please let us know and we can discuss that.” *Id.* The government thanked Fresenius for its February 27 correspondence and said it “look[ed] forward to receiving the index” of lawyers on the log (Exs. 81-82), but it never

responded to Fresenius' offer to discuss the roles of non-lawyers on the emails (Exs. A, B).

The Court should not require Fresenius to provide this additional information about the hundreds of non-legal personnel on its logs. It would be a massive burden, and the government has made no showing that this extreme relief is necessary to avoid prejudice. Much of the information is already available to the government from multiple sources: (1) Fresenius provided the job titles of all email custodians to the government when discussing custodians (Exs. 16, 19, 36, 44, 45; ECF 3-1, 3-2); (2) Fresenius has produced more than 200 pages of organization charts (Exs. 2, 3, 46); and (3) Fresenius has produced searchable emails that contain the requested information, including in routinely-used email signatures providing job titles.

#### **4. GDPR Documents**

The government also argues that Fresenius "fail[ed] to provide [a] log explaining its basis for withholding the GDPR Documents." ECF 2, p. 39. The government cites no case requiring such a log. Nor does it cite a case holding that Fresenius' proposed solution for the GDPR issue is not sufficient. As discussed above, the DOJ accepted Fresenius' suggested approach in another matter. Exs. 127, 129. On September 10, 2019, Fresenius offered to the Middle District of Tennessee to follow this same approach. Ex. 113. Here, the government ignored Fresenius' proposal. Exs. A, B.

## F. *In Camera* Review

The government also requests an *in camera* review. It has not met the standards necessary to support that such a review is necessary. The request relies heavily on the fact that 12,500 documents have been logged. This total is a small percentage of the overall production. The number of documents on the log is proof only of the overbreadth and burden of the government's document requests. FreseniusRx is a large commercial business that recently entered the heavily regulated pharmacy industry, requiring regular use of lawyers. By relying only on the number of documents logged without recognizing the circumstances, the government's request has no support other than speculation. *Armouth Int'l, v. Dollar Gen. Corp.*, 2015 WL 6696367, at \*3-4 (M.D. Tenn. 2015) ("unsupported speculation" does not justify an *in camera* review).<sup>3</sup>

Nevertheless, Fresenius does see certain benefits from *in camera* review. It would provide some degree of Court supervision of the government's overbroad discovery. Should the Court believe that an *in camera* review is appropriate to decide these issues, Fresenius requests the right to participate. It would be able to provide any additional context needed for the Court to make a privilege decision. Hearings conducted by the judicial officer would also allow Fresenius to answer any questions about the background of the documents that the officer might have. *In re Grand Jury Investigation No. 83-2-35*, 723 F.2d 447, 454 (6th Cir. 1983); *U.S. v. Hanna*, 661 F.3d 271, 295 (6th Cir. 2011) ("This court has reviewed all of the information that was presented to the district judge *ex parte* and *in camera*, as well as the proceedings at those hearings. We conclude that the

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<sup>3</sup> A major reason for the number of logged items is that documents became "responsive" and required logging solely by virtue of words and phrases in them "hitting" on the expansive and overbroad search terms requested by the government. For example, the government insisted on search terms such as "complain\*" (Ex. 48) which generated "hits" in many privileged documents on regulatory issues that can have no relationship to the underlying issues. Fresenius believes a judicial officer with knowledge of the *qui tam* complaint and the search terms will quickly grasp this circumstance.

withheld information was properly found to be privileged.”). Fresenius also requests that it or the Magistrate Judge be made aware of the contents of the underlying *qui tam* complaint in order to assess whether logged documents have any relevance to the matter at hand. A hearing might also require the government to articulate why specific privilege log entries are insufficient. Fresenius offered to have such a discussion with the government (Ex. 116; ECF 3-17), but the government declined (Exs. A, B). At this point, Fresenius would be appreciative of having Court supervision of the discovery being sought such as might be obtained via *in camera* review.

#### IV. CONCLUSION

For the reasons set forth above, the Petition should be denied. If the Court determines that some judicial oversight is appropriate, Fresenius recommends an *in camera* review by a judicial officer as described above.

Date: April 24, 2020

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 24th day of April 2020, I electronically filed the foregoing Opposition To Petition To Enforce Inspector General Subpoenas with the Clerk of Court using the CM/ECF system, which sent notification of the filing to all counsel of record, including the following:

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